

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "As An Astringent Douche For Leucorrhea" was false and misleading since it suggested and implied that the article was effective in the treatment of leucorrhea, whereas the article was not effective for such purpose; and, Section 502 (b) (2), the article failed to bear a label containing an accurate statement of the quantity of the contents (the article was short of the declared weight).

DISPOSITION: April 30, 1951. Default decree of condemnation and destruction.

DRUG FOR VETERINARY USE

3420. Misbranding of Tuttle's American Condition Powders. U. S. v. 138 Boxes * * *. (F. D. C. No. 30373. Sample No. 86630-K.)

LABEL FILED: January 8, 1951, Southern District of California.

ALLEGED SHIPMENT: On or about October 24, 1950, by the Tuttle's Elixir Co., from Boston, Mass.

PRODUCT: 138 boxes of *Tuttle's American Condition Powders* at Los Angeles, Calif.

LABEL, IN PART: (Box) "9 oz. when Packed Tuttle's American Condition Powders Keep Your Horse in Good Condition * * * Fabricated from the Following Ingredients Charcoal, African Ginger, Iron Sulphate, Gentian Root, Quassia Chips, Magnesium Sulphate, Fenugreek, Fennel, Soda Bicarbonate, Elm Bark, Yellow Bark, Sulphur, Salt, Salt-Petre, Middlings."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements on the label of the article were false and misleading since the article was not effective for the purposes stated and implied: "* * * Condition Powders Keep Your Horse in Good Condition * * * When horse is thin and appetite is not improving, double the dose, morning and night * * * Condition Powders Used for All Forms of Indigestion. It increases the digestive fluids in the stomach. It assists peristalsis action of the intestines, thereby being a resistant to digestive disturbances. It enriches the blood and serves to keep the blood stream through the different organs of the body in proper tolerance. It can be profitably used in connection with the following conditions:—Loss of appetite, improvement of the skin and coat, overwork, exhaustion, nervousness, overfeeding, urinary troubles, inorganic conditions of the kidney and urinary organs, is an assurance against cholic, and will regulate the bowels. Incapacities resulting from impaired digestion will be prevented by the timely use of Tuttle's American Condition Powders, and is useful in the convalescent stages of other diseases arising from indigestion."

Further misbranding, Section 502 (b) (2), the article failed to bear a label containing an accurate statement of the quantity of the contents (the article was short of the declared weight); and, Section 502 (c), the information required by law to appear upon the label, namely, the names of the active ingredients of the article, was not placed thereon with such conspicuousness and in such terms as to render it likely to be understood by the ordinary individual under customary conditions of purchase and use since the names of such active ingredients were interspersed among the names of inert ingredients.

DISPOSITION: February 14, 1951. Default decree of condemnation and destruction.

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3421-3440

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency, and include, where indicated, the results of investigations of the Agency, prior to the institution of the proceedings. Published by direction of the Federal Security Administrator.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *September 26, 1951.*

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*For presence of a habit-forming narcotic without warning statement, see No. 3423; omission of, or unsatisfactory, ingredients statements, Nos. 3422, 3424-3427, 3429; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 3422-3427, 3429, 3440; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 3422, 3423, 3425-3427, 3429, 3440.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS**- DRUGS FOR HUMAN USE**

3421. Misbranding of Estinyl tablets, Hormotone "T" tablets, Oreton-M tablets, Neo-Hombreol tablets, and Metandren Linguets. U. S. v. Ace Mail Order Co. and Mendel Bernstein. Pleas of nolo contendere. Each defendant fined \$750. (F. D. C. No. 29421. Sample Nos. 4737-K, 19885-K, 19888-K, 19893-K to 19895-K, incl.)

INFORMATION FILED: June 27, 1950, District of New Jersey, against the Ace Mail Order Co., a partnership, East Orange, N. J., and Mendel Bernstein, a partner in the firm.

ALLEGED SHIPMENT: On or about June 2 and 24 and July 11, 1949, from the State of New Jersey into the States of Massachusetts and Tennessee.

LABEL, IN PART: "Schering Tablets Estinyl * * * Brand of Ethinyl Estradiol * * * Each tablet contains 0.05 mg. Crystalline Pure Ethinyl Estradiol Schering Corporation Bloomfield, New Jersey," "Schering Estinyl tablets .05 m. g.," "Hormotone 'T' Estrogenic Hormones * * * Each tablet contains estrogens (estradiol, estrone) equivalent to 1,000 International Units and 1/20 gr. thyroid * * * G. W. Carnrick Co. Newark, N. J.," "Schering Oreton-M * * * Brand of Methyl Testosterone Crystalline pure testicular hormone preparation * * * Schering Corporation Bloomfield, New Jersey * * * Each tablet contains 10 mg. Methyl Testosterone," "Tablets 10 mg. each Neo-Hombreol (M) 'Roche-Organon' * * * (Androgenic Preparation—Brand of Methyl Testosterone) * * * Roche-Organon, Inc. Nutley, New Jersey Organon, Inc. Formerly known as Roche-Organon, Inc. Orange, New Jersey," and "Metandren Linguets Brand of Methyltestosterone U. S. P. * * * 10 mg. * * * Ciba Pharmaceutical Products, Inc. Summit, New Jersey."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use since the labeling bore no directions for use.

Further misbranding, Section 502 (f) (2), the labeling of the articles failed to bear such adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and duration of administration in such manner and form as are necessary for the protection of users. The labeling of the *Estinyl tablets* failed to warn that their use by the male may result in sterility and loss of sexual power and may have a feminizing effect upon the male; that their use by the female may result in sterility, injury to the female generative system, and bleeding from the uterus; and that their use by females with carcinoma of the breast, cervix, and uterus may result in acceleration of malignant growth. The labeling of the *Hormotone "T" tablets* bore no warnings against unsafe dosage and duration of administration. The labeling of the *Oreton-M tablets*, *Neo-Hombreol tablets*, and *Metandren Linguets* failed to warn that the use of such tablets and linguets may result in sterility and that their use by individuals with carcinoma of the prostate may result in acceleration of the malignant growth.

DISPOSITION: March 30, 1951. Pleas of nolo contendere having been entered, the court imposed a fine of \$750 against each defendant.